K061360

SECTION II

JUN 27 2006

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Submitter:

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Contact Person:

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Manager, Regulatory Affairs
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Preparation Date:

May 11, 2006

Device Information:

Device Classification Name:	Immunohistochemistry Assay, Antibody, Estrogen Receptor
Common/Usual Name:	Antibody for detection of estrogen receptor in histological tissue sections
Proprietary Name:	NeoMarkers Rabbit Monoclonal Anti-Human Estrogen Receptor Antibody (Clone SP1)
Regulation Number:	21 CFR§864.1860
Product Code:	MYA
Regulatory Class:	Class II

Predicate Devices:

NeoMarkers Rabbit Monoclonal Anti-Human Estrogen Receptor Antibody (Clone SP1) is substantially equivalent to the Ventana ER Primary Antibody (Clone 6F11) (K984567) for its stated intended use.

Device Description:

Lab Vision's NeoMarkers Rabbit Monoclonal Anti-Human Estrogen Receptor (ER) Antibody (Clone SP1) binds to ER in the paraffin embedded tissue section. The specific antibody is localized by a biotin conjugated secondary antibody formulation that recognizes rabbit immunoglobulins. This step is followed by the addition of an avidin/streptavidin enzyme conjugate that binds to the biotin present on the secondary antibody. The specific antibody secondary antibody avidin/streptavidin enzyme complex is then visualized with a precipitating enzyme reaction product, which is readily detected by light microscopy. Each step is incubated for a precise time and at room temperature. At the end of each incubation step, the Lab Vision automated slide stainer (Lab Vision Autostainer) washes the sections to stop the reaction and remove unbound material that would interfere the desired reaction in subsequent steps.

Intended Use:

NeoMarkers Rabbit Monoclonal Anti-Human ER Antibody (Clone SP1) is an immunohistochemical (IHC) assay intended for laboratory use for the qualitative detection of ER antigen by light microscopy in sections of formalin fixed, paraffin embedded normal and neoplastic tissues on a Lab Vision automated slide stainer. It is indicated as an aid in assessing the likelihood of response to therapy as well as in the prognosis and management of breast cancer patients.

Comparison to Predicate Device(s):

NeoMarkers Rabbit Monoclonal Anti-Human ER Antibody (Clone SP1) is substantially equivalent to the Ventana ER Primary Antibody (Clone 6F11) (K984567) for its stated intended use.

Device Characteristics	Subject Device	Predicate Device (K984567) (K990618)
Intended Use	NeoMarkers Rabbit Monoclonal Anti-Human ER Antibody (Clone SP1) is an immunohistochemical (IHC) assay intended for laboratory use for the qualitative detection of ER antigen by light microscopy in sections of formalin fixed, paraffin embedded normal and neoplastic tissues on a Lab Vision automated slide stainer. It is indicated as an aid in assessing the likelihood of response to therapy as well as in the prognosis and management of breast cancer patients.	Ventana ER Primary Antibody (Clone 6F11) is intended for laboratory use for the qualitative detection of ER antigen in sections of formalin fixed, paraffin embedded tissue of a Ventana automated immunohistochemistry slide staining device. It is indicated as an aid in the management, prognosis and prediction of therapy outcome of breast cancer.
Target Epitop	Estrogen Receptor	Estrogen Receptor
Clone	Rabbit Monoclonal Ab (Clone SP1)	Murine Monoclonal Ab (Clone 6F11)
Matrix	Tissue (Breast)	Tissue (Breast)
Storage	2°C to 8°C until expiration date	2°C to 8°C until expiration date
Stability	Until expiration date noted package	Until expiration date noted on package

Summary:

The information provided in this pre-market notification demonstrates that NeoMarkers Rabbit Monoclonal Anti-Human ER Antibody (Clone SP1) is substantially equivalent to the Ventana ER Primary Antibody (Clone 6F11), the previously cleared predicate device (K984567). Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate device. The information supplied in this pre-market notification provides reasonable assurance that NeoMarkers Rabbit Monoclonal Anti-Human ER Antibody (Clone SP1) is safe and effective for it's stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Grace Hsiao-Fen Chang
Manager, Regulatory Affairs
Lab Vision Corporation
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Fremont, California 94539

JUN 27 2006

Re: k061360
Trade/Device Name: NeoMarkers Rabbit Monoclonal Anti-Human ER Antibody (Clone SPI)
Regulation Number: 21 CFR § 864.1860
Regulation Name: Immunohistochemistry
Regulatory Class: II
Product Code: MYA
Dated: May 11, 2006
Received: May 16, 2006

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

SECTION III

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K061360

Device name: NeoMarkers Rabbit Monoclonal Anti-Human ER Antibody (Clone SP1).

Indications for Use:

NeoMarkers Rabbit Monoclonal anti-Human ER Antibody (Clone SP1) is an immunohistochemical (IHC) assay intended for laboratory use for the qualitative detection of ER antigen by light microscopy in sections of formalin fixed, paraffin embedded normal and neoplastic tissues on a Lab Vision automated slide stainer. It is indicated as an aid in assessing the likelihood of response to therapy as well as in the prognosis and management of breast cancer patients.

PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the Counter Use_____

(per 21 CFR §801.109) (Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061360